ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

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President & CEO

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Re: Docket No. 98-N-0583 – Exports: Notification and Recordkeeping Requirements

The Animal Health Institute ("AHI") submits these comments in response to the Proposed Rule published in the Federal Register on Friday, April 2, 1999, 64 Fed. Reg. 15944, concerning new regulations to establish the recordkeeping requirements for persons exporting animal drugs. AHI is a national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines, and feed additives used in modern food production, and the medicines that keep pets healthy.

It is our understanding that only the recordkeeping provisions of this proposed rule under section 801 of the act would apply to veterinary drugs. Additionally, section 802 of the act applies only to the maintenance of records for drugs or devices and therefore is not applicable to veterinary drugs. The Animal Health Institute is pleased to have the opportunity to provide specific comments on relevant portions of this proposed rule.

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I. Introduction – AHI seeks clarification of the reference in the third paragraph to veterinary biologics, which are not subject to 21 U.S.C. regulations, rather are regulated by the United States Department of Agriculture under 9 U.S.C. As this is the only reference to veterinary biologics within this proposed rule, AHI would recommend the removal of this reference from the introduction.

II. Description of Proposed Rule – regarding proposed § 1.101(a), the proposed rule states:

> "Products that meet all applicable requirements of the act or the PHS Act for marketing and sale in the United States and are exported for the same approved indications are not subject to the export restrictions in sections 801 and 802 of the act and section 351 of the PHS Act."

Is this to be interpreted that a product meeting all applicable requirements for marketing in the U.S. but labeled in a foreign language, including the same U.S. approved indications, would not be subject to the record keeping requirements of this proposed rule?

"§ 1.101(b)(1) would require records describing or listing the product specifications requested by the foreign purchaser...." AHI's interpretation of this requirement is that the foreign purchaser will provide the specifications for the product he wants to import one time and this will be kept on file at the manufacturing site for reference and inspection. The specifications need be only as detailed as necessary to meet the purchaser's needs. If the foreign purchaser's specifications change, he will provide an amendment to the manufacturing site. We do not

interpret this proposed section to require the foreign purchaser to add product specifications to every product order. Batch records of manufacturing, which are generated for all lots of product produced, whether for domestic use or export, would be kept as they normally are and comparison during an inspection would be expected to reveal that the lots exported did meet the foreign purchaser's specifications.

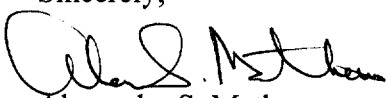
Proposed § 101.1(b)(2) would require the maintenance of records demonstrating that the product has marketing approval from the importing country's government. AHI interprets this proposed section requirement to be fulfilled if a copy of the foreign country's equivalent to an "approval letter" or "Federal Register notice of product approval" is on file at one of the offices of the manufacturer. In lieu of equivalent registration documentation, a letter from an appropriate government agency would be adequate to meet this requirement. AHI suggests that the proposed rule be amended to address the situation where a country has no registration requirement for veterinary drugs. In such case, we propose that a non-product-specific letter from the foreign purchaser stating that they have no registration requirements for the importation and use of veterinary drugs would be adequate. This is interpreted as a one-time occurrence with the letter kept on file at the manufacturing facility, until such time as regulations are instituted.

Proposed § 101.1(b)(4) would require records showing that the product is not sold or offered for sale in the United States. It is unclear what records would be required to satisfy this requirement and AHI seeks clarification. AHI proposes that copies of shipping records and

product labeling (available upon inspection) provide adequate documentation that the product is not sold or offered for sale in the United States.

AHI appreciates the opportunity to comment on this proposed rule. Our members would be pleased to participate in a dialogue with CVM and other interested parties on the development of this policy.

Sincerely,



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